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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,750	10/25/2001	Jenny Louie-Helm	3100-0003	1055

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,750	LOUIE-HELM ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,9,12-37,39,40,45-49 and 54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,9,12-37,39,40,45-49 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, request for extension of time, IDS, amendment and remarks, all filed 8/22/06. Claims 6, 7, 10, 11, 50-53, 55 and 56 are canceled. Claims 1-5, 8, 9, 12-37, 39, 40, 45-49 and 54 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/22/06 has been entered.

Response to Arguments

Any rejections not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5, 8, 9,12-37, 39, 40, 45-49 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Claim 1 is amended such that gastric retentive drug is incorporated in a matrix of at least two biocompatible, hydrophilic polymers. Applicant points to paragraphs at page 21, line 20 to page 22, line 3 and Examples 1 and 2 as providing support for the amendments to claim 1, 8, 9, 13-17 and 22. However, the paragraphs at page 21, line 20 to page 22, line 3 and Examples 1 and 2 contemplate the use of "combinations" of different polyethylene oxide with the polyethylene oxide differing in molecular weight. Examples 1 and 2 use two polyethylene oxide polymer differing in molecular weight. Thus, these paragraphs do not provide support for the new limitation of the claims. Paragraph [0051] of the published application states "at least one biocompatible, hydrophilic, erodible polymer" and not at least two.

Claim 12 recites molecular weight of "above 2,000,000" and low molecular weight of less than 2,000,000. This claim broadens the claims and the upper end for the high molecular weight is limitless or infinite. Same is true for the lower end of the low molecular weight. There is no support for polyethylene oxide having molecular weight that open ended for infinite molecular weight for the high molecular weight polymer. Similarly, the low molecular weight polymer has disclosed molecular weight range.

The above rejection may be overcome by removing the new matter from the claims. A range of molecular weight may be claimed in claim 12.

5. Claims 30-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites that the active agent is water-soluble and the water-soluble agent is rendered sparingly soluble. It is unclear how a water-soluble agent is made sparingly water soluble by a vesicle.

Specification

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claims 8 and 9 recite poly(ethylene oxide-co-propylene oxide) and the specification fails to provide support for this copolymer.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 8, 12-23, 26-34, 36, 37, 39, 40, 45-49 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Shell et al. (US 5,972,389).

Shell discloses a controlled release oral dosage form that comprises drug particles dispersed in swellable/erodible polymer where the erodible polymer is polyethylene oxide; the dosage form is formulated as tablet or capsule and liposomes or nanoparticles or enteric-coated drug particles are examples of drug containing vesicles that can deliver drugs to the site of interest (abstract, column 1, line 48 to column 2 line 36, column 3, lines 26-44, column 4, lines 5-18, column 7, lines 60-62, column 8, lines 4-55). Ciprofloxacin (column 5, line 10), bismuth subsalicylate, bismuth citrate, antibiotics such as amoxicillin, tetracycline, chlarithromycin, thiamphenicol, metronidazole which are Helicobacter pylori eradicating drugs (column 5, lines 46-49 and claims 6-9) and meets claims 26, 27 and 28; gastric lowering agents such as omeprazole, ranitidine, cimetidine, famotidine (column 5, lines 49-55) are examples of drugs delivered by the dosage form of Shell. Shell also teaches that nifedipine, acyclovir, alprazolam, phenytoin, carbamazepine, clozapine, lovastatin and nitrofurantoin are other drugs that can be delivered by the vesicle (claim 5).

The molecular weight of the polyethylene glycol in Shell ranges from 1×10^5 to 7×10^6 kD (claims 3 and 4). The weight ratio of drug to polymer is 2:3 to 9:1 (column 8, lines 26-31). Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and at least two polyalkylene oxide polymers. Shell discloses composition that contains

two types of polyethylene oxide (PEO), one PEO has a molecular weight of 2,000,000 and the other has a molecular weight of 5,000,000 (column 14, lines 14-20) meeting the molecular weight requirements of claims 1, 8, 9, 12-15. Shell teaches a range of drug to polymer and one of the points in the taught range in Shell anticipates a point in the recited range in claims 13-16. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is recited, Shell meets the limitations of the claims. Also the molecular weight of the active agent is a property of the active agent and because the instant claims have not recited any drugs that would have the molecular weight recited in instant claim 21 and because some of the drugs recited in the claims are the same as those taught by Shell, Shell meets the limitations of claim 21.

Shell contemplates the use of nanoparticles, nanospheres and enteric-coated drug particles and nanoparticles (column 2, lines 29 and 30). The disclosure of liposomes, particles and nanoparticles and nanocapsules and nanospheres (column 2, lines 29-31) meet the limitations of claims 30-33. The dosage forms of Shell are incorporated in vesicles such as liposomes, nanoparticles, protenoid microspheres, pharmacosomes, etc. and are enteric coated (column 3, lines 43-49) meeting claims 30-33. Therefore, the teachings of Shell meet the limitations of the claims.

Response to Arguments

9. Applicant's arguments filed 8/22/06 have been fully considered but they are not persuasive.

Applicant argues that shell does not teach or suggest dosage forms that contain more than one polymer.

Response:

Shell specifically discloses a dosage form comprising two drugs nifedipine and triamterine and two polyethylene oxide polymers that differ with respect to the molecular weight. Applicant is herein referred to Example 7 and column 14, lines 9-31.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shell et al. (US 5,972,389).

Shell is discussed above. Shell discloses formulations in which one of the drugs is phenytoin, an anticonvulsant drug. Shell fails to disclose composition that contains topiramate. However, topiramate is also an anticonvulsant drug. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions that contain phenytoin as the active agent and one anticonvulsant drug can be used in place of the other with the expectation of producing anticonvulsant effect in a subject.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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